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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,152	08/04/2006	James Peter Burnie	22083-008US1 / WA/MC/MP10	8989
26161 7590 06/25/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 06/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/553,152

**Applicant(s)**

BURNIE ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 14 October 2005, is acknowledged.

Claims 1-18 have been cancelled. New claims 19-36 have been added.

2. Claims 19-36 are pending and under consideration.

### **Specification**

3. The disclosure is objected to because of the following informalities:

Page 1, line 17, "colonised" should be "colonized".

Page 4, line 17, "standardisation" should be "standardization".

Page 5, lines 1 and 4, "synthesised" should be "synthesized"; line 16, "synthesising" should be "synthesizing"; line 18, "optimise" should be "optimize"; line 19, "optimising" should be "optimizing".

Page 8, line 25, "optimisation" should be "optimization".

Page 11, line 1, "characterised" should be "characterized".

Page 13, line 15, "synthesised" should be "synthesized".

Page 14, line 7, "characterised" should be "characterized".

Page 15, line 7, "immunisation" should be "immunization"; line 9, "analysed" should be "analyzed".

Page 16, lines 7 and 25, "synthesising" should be "synthesizing".

Page 17, line 2, "synthesised" should be "synthesized".

Page 23, line 22, "resynthesised" should be "resynthesized".

Page 26, line 10, "immunised" should be "immunized"; line 23, "heparinised" should be "heparinized".

Page 27, lines 7, 14, and 18 refer to a "Figure 1". There is no Figure 1.

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Page 28, line 3 refers to a "Figure 1". There is no Figure 1.

Page 30, line 1, "were removed" should be "was removed".

Page 33, line 8, "recognised" should be "recognized"; lines 11 and 14, "resynthesised" should be "resynthesized"; line 12, "codon-optimised" should be "codon-optimized"; line 14 refers to a "Figure 2". There is no Figure 2.

Page 35, line 6, "solubilised" should be "solubilized"; line 17, "localised" should be "localized".

Page 45, line 26, "has lead" should be "has led".

Appropriate correction is required.

### **Drawings**

4. The subject matter of this application (page 23) admits of illustration by drawings (Figures 1 and 2) to facilitate understanding of the invention. Applicant is required to furnish the drawings under 37 CFR 1.81(c). No new matter may be introduced in the required drawings. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

### **Double Patenting**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 19, 20, 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 15 of copending Application No. 11/630,926. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to antibody or antigen binding fragments thereof "having" SEQ ID NO:27 or SEQ ID NO:32 (instant claims) or "having" SEQ ID NO:1 or 41 (11/630,926). The open language in the recitation of the antibody/fragment "having" a particular sequence is deemed open language, i.e., comprising. Both SEQ ID NO:1 and 41 "comprise" SEQ ID NO:27.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 22 is drawn to a method for identifying candidate antibody sequences specific for a *C. difficile* antigen or "a vaccine" by isolated B-cells from a patient infected by *C. difficile* and correlating sequences of antibodies specific for said antigen or vaccine.

The language of the claim, i.e., "a vaccine" and not "a vaccine against *C. difficile* infection" thus encompasses any/all vaccines. It is unclear then how one identifies specific antibodies against any/all vaccines by using B-cells from only *C. difficile* patients.

Claims 23-36 depend from claim 22, but do not clarify the issue.

9. Claims 22-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods of identify sequences of antibodies with specific activity by "correlating" the sequences. It is unclear what is encompassed by this "correlating" in terms of steps, results, etc.

10. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to the metes and bounds of what constitutes a "pronounced" antibody response.

### **Conclusion**

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

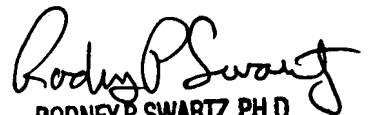
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272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

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June 18, 2007